

REMARKS

The Office has indicated in the Action that the claims 1-7 are pending and under examination. However, Applicants had submitted a preliminary amendment on June 18, 2007, by which claims were amended and two new claims, claims 8-9, were added. Accordingly, Applicants respectfully request that the Office recognize that claims 1-9 are pending and should also be under examination.

With this amendment, claims 1, 4 and 7 have been amended. Support for these amendments can be found throughout the specification and at, for example, Figure 2 and previously presented claims. No new matter has been added. Reexamination and reconsideration in light of the forgoing amendments and following remarks is respectfully requested.

I. CLAIM REJECTIONS UNDER 35 USC § 112, SECOND PARAGRAPH

Claims 1, 4 and 7 stand rejected under 35 USC § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Office suggests adding chemical structures to claims 1 and 4.

Applicants have amended the claims to address the Office's points. The Office is also invited to see the definition of the term "reduced isoalpha acid" (e.g., dihydro-isohumulone, dihydro-isocohumulone and dihydro-isoadhumulone) in the specification as filed on page 9, paragraph [035]. As such, the Applicants submit that the requirements of 35 USC § 112, second paragraph have been met and respectfully request withdrawal of this rejection.

II. CLAIM REJECTIONS UNDER 35 USC § 102(e)

Claims 1-3 stand rejected under 35 USC § 102(e) as being anticipated by Shahlal et al. (US 6,583,322). The Office states that Shahlal et al. disclose compositions comprising a reduced isoalpha acid (RIAA) and isoalpah acid (IAA) in "FIG.1; FIG.2; column 1, lines 14-24 and 60-63; and column 4, lines 2-25." The Office further alleges that "[i]t is disclosed that compositions therein which are mixtures of DHIA and IAA remained clear liquids at all ratios between about 1

and 99%, and comprise at least 0.1% of the composition. See column 18, lines 15-45.”

Applicants respectfully traverse for at least the following reasons.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. [] Anticipation of a patent claim requires a finding that the claim at issue "reads on" a prior art reference. [] Specifically, when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim. [] ("It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art."). In chemical compounds, a single prior art species within the patent's claimed genus reads on the generic claim and anticipates.” See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d at 1346; 51 USPQ2d 1943 (Fed. Cir. 1999) (internal citations deleted); See also MPEP 2131.03 (I).

Applicants submit that the range disclosed in Shahlal *et al.* does not fall within the ratios presently claimed and, therefore, Shahlal *et al.* cannot be an anticipatory reference.

FIG.1 in Shahlal *et al.* is only a “depiction of the structural formulas of cis and trans IA and DHIA” as described in the figure description in col. 14, lines 30-31. FIG.2 in Shahlal *et al.* is also a “depiction of the structural formulas of cis and trans THIA and HHIA” as described in col. 14, lines 32-33. Neither of these figures teaches or suggests that the structures are in a mixture; nor do they disclose any ratios or ranges of a mixture (if any).

In column 1, lines 14-24, Shahlal *et al.* generally describe IA, DHIA, THIA and HHIA and their analogs. They make no reference to any ratios or ranges of a mixture of IA and DHIA.

In column 1, lines 60-63, again Shahlal *et al.* make no reference to any ratios or ranges of a mixture of IA and DHIA. By stating that “[i]n these commercial preparations, the hop acids, and particularly 30% IA and 35% DHIA, as potassium salts at pH 10 or above in water, act as co-solvents for themselves” (emphasis added), Shahlal *et al.* make a reference to the lines above where they wrote that “IA is sold as a 30% solution of its potassium salt at a pH of about 10 in water. DHIA is sold as a 35% solution of its potassium salt in water at pH of about 10.5 and above, . . .” See col. 1, lines 49-52. Therefore, the phrase “30% IA and 35% DHIA” if read

within its context (clo. 1, lines 49-63) means that each of these preparation act as its own co-solvent at pH 10 or above.

In column 4, lines 2-25, Shahlal *et al.* make no reference to any ratios or ranges of a mixture IA and DHIA when they write “[t]he objects of this disclosure are . . . to provide . . . [n]on-precipitating mixtures of DHIA and/or HHIA solutions with added IA and THIA.”

In column 18, lines 15-45, Shahlal *et al.* make no reference to a ratio or range of a mixture of IA and DHIA that falls within the ratios presently claimed. Table 5-1, shows no mixing of IA and DHIA. Only in lines 36-38, Shahlal *et al.* make a general statement that “[m]ixtures of the DHIA and THIA and/or IA were compatible and remained clear liquids at all ratios between 1 and 99%.” Although the “ratios between 1 and 99%” may cover the claimed ratios of ‘RIAA (i.e., dihydroiso alpha acids) and IAA of about 3:1 to about 1:10’, Shahlal ratios not fall within the claimed ratios and, therefore, cannot anticipate them.

Accordingly, Applicants submit that because the claimed ranges of RIAA and IAA are narrower than the ranges disclosed in Shahlal *et al.*, claims 1-3 do not read on Shahlal *et al.* and are not anticipated by that reference. As such Applicants respectfully request that this rejection be withdrawn.

III. CLAIM REJECTIONS UNDER 35 USC § 103(a)

Claims 1-7 stand rejected under 35 USC § 103(a) as being unpatentable over Kuhrts (US 2004/0137096, herein after “Kuhrts”).

The Office contends that “Kuhrts teaches a pharmaceutical composition comprising hops extract consisting of iso-alpha acids (IAA), and reduced iso-alpha acids (RIAA) such as . . . dihydroiso-humulone, . . . and combinations thereof. It is also disclosed that iso-alpha acids which are combinations of reduced isoalpha acid (RIAA) and isoalpha acid (IAA) will be present in an amount of 5.05% to 10% by weight in the hops extract.” Office Action, page 5.

The Office acknowledges that “Kuhrts does not expressly teach the ratio of reduced isoalpha acid:isoalpha acids about 3:1 to about 1:10, in the composition. Kuhrts does not expressly teach that the composition contains at least 0.1% of RIAA and IAA individually.”

Office Action, page 5. Nevertheless, the Office concludes that “[i]t would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the reduced isoalpha acid and isoalpha acid employed in the composition of Kuhrts, to obtain a desired effect such as reducing inflammation.” Office Action, page 6. Applicants respectfully traverse.

Applicants submit that they have unexpectedly discovered that compositions of reduced isoalpha acids (i.e., dihydro isoalpha acids) and isoalpha acids, when combined in certain amounts and ratios, have synergistic anti-inflammatory effects. See the entire application as filed and, for example, the title and abstract and Example 4. Accordingly, the claims reflect the finding of synergism. Kuhrts does not teach or suggest the element of “synergy” as claimed or taught by the present invention.

Applicants describe in their application that “synergy was noted for all RIAA:IAA combinations, albeit at different segments of the dose-response curves.” See Example 4 of the application as filed on page 31, paragraph 104 to page 32. This unexpected finding showed that while RIAA and IAA could act synergistically over a wide range of ratios and concentrations as shown in Figures 4A-H of the specification, they could also act additively or even antagonistically at certain other concentrations. See Figures 4A-H for tabulated CI (Combination Index) values and the specification on pages 30-31, paragraph [0100], which defines CI values of <1 , $=1$, and >1 to indicate synergism, additivity and antagonism, respectively.

Thus, in view of the present specification, the synergistic property of a given combination of RIAA and IAA was shown to be unpredictable. In KSR, the Supreme Court reaffirmed that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR*, 82 USPQ2d at 1395 1395-97 (2007); MPEP § 2141 guidelines for determining obviousness. However, as described above, by discovering synergism between the compounds claimed, Applicants have shown more than predictable results.

Furthermore, as described in Example 4 of the application and shown in Figures 4A-H, Applicants not only have discovered specific ratios in which RIAA and IAAs act synergistically (which is an effect greater than the expected sum of the additive effect of each compound taken separately), but they have also discovered to an unobvious extend that one must avoid the ratios at which the mixture of RIAA and IAA could act antagonistically.

Therefore, in view of the information disclosed in the present specification and the claims, Applicants submit that at the time of filing of the application, a skilled artisan who was familiar with the teachings of Kuhrts could not have distinguished between the additive or antagonistic and beneficially synergistic interactions of the compounds presently claimed. Accordingly, the skilled artisan would not have had a reasonable expectation of success in combining the compounds of Kuhrts or optimizing parameters to arrive at the presently claimed ratios. As such, Applicants respectfully submit that the invention as claimed is unobvious or Kuhrts and respectfully request withdrawal of the 35 USC § 103(a) rejection.

IV. DOUBLE PATENTING REJECTION

Claims 1-7 stand provisionally rejected under the doctrine of obviousness-type double patenting as claiming the similar invention as that of claims 4-7 of copending Application 10/789,814 (Applicants Ref. No. 068911- 0075).

The Applicants respectfully request that this provisional rejection be held in abeyance pending a determination of patentability of the conflicting claims.

V. CONCLUSION

On the basis of the foregoing remarks and amendments, Applicants respectfully submit that amended claims 1-9 are in condition for allowance. Passage to issue is respectfully requested.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, The Examiner is requested to call Applicants' agent at the telephone number shown below.

A Request for a Three (3) Month Extension of Time, up to and including February 12, 2009 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications to Deposit Account 50-1133. Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under 37 C.F.R. § 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectively submitted,

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A handwritten signature in black ink, appearing to read 'Atabak Royae', is written over a horizontal line.

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